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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/554,328	09/01/00	BRENNER	M 30801/7187(5

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EXAMINER	
ROARK, J	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summ ry	Application N .	Applicant(s)	
	09/654,328	BRENNER ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-9,13,16,22,24,25,30,35,36,44-46,48 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,5-9,13,16,22,24,25,30,35,36,44-46,48 and 49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's preliminary amendment, filed 9/1/00 (Paper No. 4), is acknowledged.
Claims 2, 4, 10-12, 14-15, 17-21, 23, 26-29, 31-34, 37-43 and 47 have been canceled.
Claims 1, 3, 5-9, 13, 16, 22, 24-25, 30, 35-36, 44-46 and 48-49 *are pending.*

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

4. It is noted that the claims recite a cadherin-11 inhibitory "agent" that is an antibody (to either cadherin-11 or to various cadherin-11 counter-receptor), a cadherin-11 polypeptide, or a nucleic acid molecule. These various "agents" do not share *a substantial structural feature essential to a common utility*. Thus these structurally distinct agents are subject to restriction, rather than election of species, within the context of the particular method for treating.

The restriction has therefore been set forth for methods encompassing each of these "agents" as separate groups, irrespective of the format of the claims. In addition, if additional structurally distinct "agents" are introduced during the course of prosecution that do not share *a substantial structural feature essential to a common utility* with the instantly recited "agents", then a supplemental restriction requirement may be issued.

It is further noted that claim 16 defines cadherin-11 counter-receptors to be any of "a cadherin, an integrin, a carbohydrate, and an immunoglobulin family member". Neither these counter-receptors, nor agents that bind each counter-receptor, share *a substantial structural feature essential to a common utility*. They are therefore an improper Markush grouping, subject to restriction rather than an election of species (as per MPEP 803.02). Because instant claim 16 presents counter-receptors in generic terms, rather than as defined structures, the instant Group is also defined generically. However, Applicant is reminded that a species will anticipate a claim to a genus. Further, if structurally distinct *species of* counter-receptors or agents that bind specific counter-receptors are introduced during the course of prosecution, then a supplemental restriction requirement may be issued.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 5-6, 8, 16 and 44-45, drawn to a method of treating a subject having an inflammatory joint disorder *by administering an antibody to cadherin-11*, classified in Class 424, subclass 143.1.

II. Claims 1, 5, 7-8, 16 and 44-45, drawn to a method of treating a subject having an inflammatory joint disorder *by administering an antibody to a cadherin-11 counter-receptor*, classified in Class 424, subclass dependent upon the actual counter-receptor.

III. Claims 1, 5-7, 9, 16 and 44-45, drawn to a method of treating a subject having an inflammatory joint disorder by administering a cadherin-11 polypeptide, classified in Class 514, subclass 2.

IV. Claims 1, 5, 13, 16 and 44-45, drawn to a method of treating a subject having an inflammatory joint disorder by administering a nucleic acid molecule, classified in Class 514, subclass 44.

V. Claims 22 and 24-25, drawn to a method of screening a molecular library to identify a pharmaceutical lead compound by performing an adhesion assay between a first cell and a second cell, classified in Class 435, subclass 7.21.

VI. Claims 30 and 35-36, drawn to a method of screening a molecular library to identify a pharmaceutical lead compound by performing an adhesion assay between cadherin-11 and a cadherin-11 counter-receptor, classified in Class 435, subclass 7.8.

VII. Claims 46 and 48-49, drawn to a method of screening a molecular library to identify a pharmaceutical lead compound by screening for modulation of a cellular function in a cadherin-11 expressing cell, classified in Class 436, subclass 63.

6. Groups I-VII are different methods. Each method differs from the others with respect to ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

8. This application contains claims directed to the following patentably distinct species of the claimed Inventions I, III and IV: wherein the counter-receptor is:

A) a cadherin,
B) an integrin,
C) a carbohydrate, or
D) an immunoglobulin family member.

These species are distinct because, as noted supra, each genus of counter-receptor differs in structure. In addition, each counter-receptor has a different mode of action.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions I, II, III, IV and VII: wherein the cellular function is:

A) cell proliferation,
B) factor secretion,
C) apoptosis,
D) migration, or
E) attachment.

These species are distinct because an assay for each cellular function requires different method steps.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 (Groups I, II, III and IV) and claim 46 (Group VII) are generic.

10. This application contains claims directed to the following patentably distinct species of the claimed Inventions V: wherein the first cell type is:

A) a type A synoviocyte,
B) a type B synoviocyte,
C) a synovial derived fibroblast,
D) a synovial membrane lining cell, or
E) an osteoblast.

These species are distinct because each cell differs in phenotype and/or functional properties.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

11. This application contains claims directed to the following patentably distinct species of the claimed Inventions V: wherein the second cell type is:

A) a type A synoviocyte,
B) a type B synoviocyte,
C) a synovial derived fibroblast,
D) a synovial membrane lining cell,
E) an osteoblast,
F) a T lymphocyte,
G) a B lymphocyte,
H) a plasma cell,
I) a dendritic cell,
J) a macrophage,
K) a mast cell, or
L) a natural killer cell.

These species are distinct because each cell differs in phenotype and/or functional properties.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

12. This application contains claims directed to the following patentably distinct species of the claimed Inventions VII: wherein the factor secreted is:

A) stromelysin,
B) collagen,
C) collagenase, or
D) IL-6.

These species are distinct because each secreted factor is structurally and functionally distinct, and requires different method steps to detect its secretion.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 is generic.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Technology Center 1600
October 19, 2001

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